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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/435,733 11/08/99 GALDES

A CIBT-P02-052

028120  
ROPES & GRAY  
ONE INTERNATIONAL PLACE  
BOSTON MA 02110-2624

HM12/0426

EXAMINER

BRANNICK, M

ART UNIT PAPER NUMBER

*15*

1646

DATE MAILED:

04/26/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.  
09/435,733

Applicant(s)

Galdes et al.

Examiner  
Micha I Brannock, Ph.D.

Art Unit  
1646



-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 24, 2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-51 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-51 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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***Status of Application: Claims and Amendments***

1. Claims 1-51 are pending.
2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michael Brannock, Group Art Unit 1646.

***Election/Restriction***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, 13-23, 30, 31, 41, 44-51, as the claims relate to a Sonic hedgehog polypeptide, drawn to methods of treatment or prevention using a Sonic hedgehog polypeptide, classified in class 514, subclass 2.
  - II. Claims 1-14, 16-23, 30, 31, 41, 44-51, as the claims relate to a Desert hedgehog polypeptide, drawn to methods of treatment or prevention using a Desert hedgehog polypeptide, classified in class 514, subclass 2.
  - III. Claims 1-11, 13-14, 16-23, 30, 31, 41, 44-51, as the claims relate to an Indian hedgehog polypeptide, drawn to methods of treatment or prevention using an Indian hedgehog polypeptide, classified in class 514, subclass 2.

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- IV. Claims 1-10, 16-23, 30, 31, 41, 44-51, as the claims relate to a tiggie-winkle hedgehog polypeptide, drawn to methods of treatment or prevention using a tiggie-winkle hedgehog polypeptide, classified in class 514, subclass 2.
- V. Claim 24-29, 35-40 and 42, drawn to methods of treatment or prevention using a ptc therapeutic which is a small organic molecule and associated compositions, classification dependent on the chemical nature of the ptc therapeutic.
- VI. Claims 32, 33, 34, drawn to methods of treatment or prevention using antisense nucleic acids, classified in class 536, subclass 24.5.
- VII. Claim 43, drawn to gene therapy, classified in class 514, subclass 44.

4. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VII are directed to methods that are distinct both physically and functionally, require different starting materials, and are not required one for the use of the other. Although the searches of each of the groups would overlap those of the others, no two searches would not be coextensive. Further, a search of any one of the groups could not be relied upon to provide art that might anticipate or render obvious the claims of any other group.

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Therefore, a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent.

5. The claims of Groups I-VII are generic to a plurality of disclosed patentably distinct species of treatments for different conditions - each of such conditions being defined as that afflicting a single identifiable patient population; for example, cisplatin induced neuropathy would be considered to be condition that afflicts a single identifiable patient population.

Applicant is required to elect for prosecution a single condition represented by a single identifiable patient population - such a population being required for a search of the claimed invention.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB   
April 24, 2001

  
Michael Brannock  
Primary Examiner